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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,523	02/28/2002	Jeffrey Charles Trewella	JCT002	7718

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/24/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,523

Applicant(s)

TREWELLA, JEFFREY CHARLES

Examiner

Ruth A. Davis

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 11 – 22 in Paper No. 3 is acknowledged. The traversal is on the grounds that the restriction should in fact be an election of species not an election between different inventions and that the two inventions should be searched together and rejoined. This is not found persuasive because as stated in the previous action, the two groups are not the same invention as they have separate classification and because a reference that would anticipate one would not necessarily anticipate or even make obvious the other.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11 – 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 and its dependents claim to be drawn to a method for paying storage costs of umbilical cord blood, however are rendered vague and indefinite because the dependent claims are appear drawn to a method for storing blood. It is unclear if applicant's invention is a method

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of paying/financing, or a method of storing/processing cord blood, since the recited steps are not consistent with the recited preamble of the claim. Moreover, it is unclear how recovering, concentrating, diluting, purifying, amplifying, or stabilizing cord blood achieves the method for paying storage costs.

Claims 19 and 20 are rendered vague and indefinite for reciting “amplifying” because it is unclear what applicant means by this term, as it is not adequately defined by the claim language or specification. The term is typically associated with cells, not tissues and/or organs. Moreover, it is unclear how one would “amplify” cord blood.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 11 – 14 and 21 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzalez-Ryan et al. (Pediatric Nursing 2000) in view of Annas (New England Journal of Medicine, 1999).

Applicant claims a method for paying storage costs of cord blood, the method comprising dividing the blood into 2 portions, selling one portion and using the monies made to pay for the

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second portion. The method further includes recovering the blood from a donor followed by concentrating and stabilizing the blood before dividing the cord blood.

Gonzalez-Ryan discloses the costs of storing cord blood and options for paying storage costs (p.106). The blood is collected, stabilized (p.107) and concentrated (p.108).

Gonzalez-Ryan does not specifically teach the method of payment as claimed. However, Annas discloses companies selling cord blood for therapeutic use in the event a donor cannot pay the storage costs (p.1524). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to pay for storing cord blood in any way available, since it was known to be costly. Moreover, one of ordinary skill in the art would have been motivated by Annas to sell cord blood in order to pay storage costs, as it was known to have monetary value as evidenced by Annas.

6. Claims 11 – 14 and 17 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over “Blood Plasma Pooling” (2001) in view of Annas (New England Journal of Medicine, 1999).

Applicant claims a method for paying storage costs of cord blood, the method comprising dividing the blood into 2 portions, selling one portion and using the monies made to pay for the second portion. The method further includes recovering the blood from a donor followed by concentrating, purifying and amplifying the blood before dividing the cord blood.

“Blood Plasma Pooling” teaches methods wherein blood is collected, purified, filtered, concentrated and pooled (amplifying) before dividing into aliquots for storage (p.1 – 5).

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“Blood Plasma Pooling” does not teach the method of payment as claimed. However, Annas discloses companies selling cord blood for therapeutic use in the event a donor cannot pay the storage costs (p.1524). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to pay for storing cord blood in any way available, since it was known to be costly. Moreover, one of ordinary skill in the art would have been motivated by Annas to sell cord blood in order to pay storage costs, as it was known to have monetary value as evidenced by Annas.

7. Claims 11 – 14, 17 – 18 and 21 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kline (1998) and/or Wolf, Jr (US 6059968) in view of Annas.

Applicant claims a method for paying storage costs of cord blood, the method comprising dividing the blood into 2 portions, selling one portion and using the monies made to pay for the second portion. The method further includes recovering the blood from a donor followed by concentrating, purifying and stabilizing the blood before dividing the cord blood.

Kline teaches methods where cord blood is collected, stabilized, fractionated (purified) and concentrated (p.824). Kline discloses storing cord blood and the idea of selling the cord blood for profit when one can no longer pay for storage (p.827).

Wolf, Jr. teaches methods of processing and storing cord blood wherein the blood is collected, concentrated, purified and stabilized prior to dividing and storage (col.1 line 16-25, col.4 line 29-41).

The references do not teach the method of payment as claimed. However, Annas discloses companies selling cord blood for therapeutic use in the event a donor cannot pay the

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storage costs (p.1524). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to pay for storing cord blood in any way available, since it was known to be costly. Moreover, one of ordinary skill in the art would have been motivated by Annas to sell cord blood in order to pay storage costs, as it was known to have monetary value as evidenced by Annas.

8. Claims 11 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyse et al. (US 6569427 B1) in view of Annas.

Applicant claims a method for paying storage costs of cord blood, the method comprising dividing the blood into 2 portions, selling one portion and using the monies made to pay for the second portion. The method further includes recovering the blood from a donor followed by concentrating, diluting, purifying, amplifying and stabilizing the blood before dividing the cord blood.

Boyse teaches methods for storing cord blood, the method comprising collecting blood, stabilizing, concentrating, purifying (col.18), diluting and amplifying (col.18-19) fractions of the blood for cryogenic storage.

The references do not teach the method of payment as claimed. However, Annas discloses companies selling cord blood for therapeutic use in the event a donor cannot pay the storage costs (p.1524). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to pay for storing cord blood in any way available, since it was known to be costly. Moreover, one of ordinary skill in the art would have been motivated by

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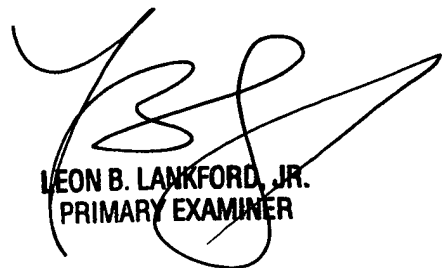
Annas to sell cord blood in order to pay storage costs, as it was known to have monetary value as evidenced by Annas.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
September 22, 2003



LEON B. LANKFORD, JR.
PRIMARY EXAMINER